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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., and JANSSEN SCIENCES IRELAND UC, Plaintiffs, v. AUROBINDO PHARMA LTD., and AUROBINDO PHARMA USA INC. Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (together, "Janssen" or "Plaintiffs") for their Complaint against Defendants Aurobindo Pharma Ltd. ("Aurobindo Ltd.") and Aurobindo Pharma USA Inc. ("Aurobindo USA") (together, "Aurobindo" or "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Aurobindo of U.S. Patent Nos. 8,518,987 (the "'987 Patent") and 7,700,645 (the "'645 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and for a declaratory judgment of infringement of U.S. Patent Nos. 7,126,015 (the "'015 Patent") and 7,595,408 (the "'408 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Aurobindo's filing of Abbreviated New Drug Application No. 21-0677 (the "ANDA"), supported by Drug Master File No. 31358 (the "DMF"), seeking approval to sell generic versions of Janssen's highly successful PREZISTA® (darunavir) 600 mg and 800 mg tablets (the "ANDA Products") prior to the expiration of the '987 Patent, the '645 Patent, the '015 Patent, and the '408 Patent (together, the "patents-in-suit").

THE PARTIES

3. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

4. Plaintiff Janssen Sciences Ireland UC is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

5. On information and belief, Aurobindo USA is a Delaware corporation with a principal place of business in East Windsor, New Jersey. On information and belief, Aurobindo USA is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Aurobindo USA is a wholly owned subsidiary, alter ago, and agent of Aurobindo Ltd.

6. On information and belief, Aurobindo Ltd. is a company organized and existing under the laws of India, with a registered office at Plot #2, Maitrivihar, Ameerpet, Hyderabad – 500 038, Telangana, India. On information and belief, Aurobindo Ltd. is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary, alter ego, and agent, Aurobindo USA. On information and belief, Aurobindo Ltd. is the holder of the ANDA and the DMF.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. On information and belief, this Court has personal jurisdiction over Aurobindo USA, *inter alia*, because Aurobindo USA's principal place of business is located in New Jersey.

9. On information and belief, this Court has personal jurisdiction over Aurobindo USA because Aurobindo USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo USA has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

10. On information and belief, Aurobindo USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

11. On information and belief, Aurobindo USA is registered to do business in

New Jersey as a foreign corporation and has appointed an in-state registered agent for service of process pursuant to N.J.S.A. § 14A:4-1(1).

12. On information and belief, Aurobindo USA has recently invoked this Court's jurisdiction in a Hatch-Waxman action. *See Aurobindo Pharma USA Inc. et al. v. Apicore US LLC et al.*, Case No. 1:16-cv-03358-RMB-KMW (D.N.J. Jun. 9, 2016). On information and belief, Aurobindo USA has also previously consented to personal jurisdiction in this district in Hatch-Waxman actions. *See, e.g.*, Answer (Dkt. No. 18) at ¶ 21, *Astrazeneca AB et al. v. Aurobindo Pharma Ltd. et al.*, Case No. 3:13-cv-07298-MLC-TJB (D.N.J. Feb. 23, 2015) ("Aurobindo admits that Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. consent to jurisdiction in this Court and does not object to venue for this particular action."); Answer (Dkt. No. 10) at ¶ 9, *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Case No. 1:14-cv-03306-JBS-KMW (D.N.J. Nov. 14, 2014) ("Aurobindo Pharma USA admits that this Court has personal jurisdiction for the purposes of this action.").

13. On information and belief, Aurobindo USA acts as the agent and alter ego of Aurobindo Ltd. On information and belief, Aurobindo USA has submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Aurobindo Ltd., including the ANDA seeking FDA approval to market Aurobindo's ANDA Products before expiration of the patents-in-suit.

14. On information and belief, Aurobindo USA and Aurobindo Ltd. operate and act in concert as an integrated, unitary business.

15. On information and belief, this Court has personal jurisdiction over Aurobindo Ltd. because Aurobindo Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court

here. On information and belief, acting itself and/or through its wholly owned subsidiary, alter ego, and agent, Aurobindo USA, Aurobindo Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

16. On information and belief, Aurobindo Ltd. has a regular and established place of business located at the principal place of business of Aurobindo USA in East Windsor, New Jersey, where Aurobindo Ltd. regularly conducts business itself and/or through its wholly owned subsidiary, alter ego, and agent, Aurobindo USA.

17. On information and belief, Aurobindo Ltd., directly and/or through its subsidiary, alter ego, and agent, Aurobindo USA, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

18. On information and belief, Aurobindo Ltd. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its subsidiary, alter ego, and agent, Aurobindo USA.

19. On information and belief, Aurobindo Ltd., directly and/or through its subsidiary, alter ego, and agent, Aurobindo USA, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

20. On information and belief, Aurobindo Ltd. has recently invoked this Court's jurisdiction in Hatch-Waxman actions. *See, e.g.*, *Aurobindo Pharma Ltd. et al. v. AstraZeneca AB et al.*, Case No. 3:16-cv-05079-PGS-TJB (D.N.J. Aug. 18, 2016); *Aurobindo Pharma USA Inc. et al. v. Apicore US LLC et al.*, Case No. 1:16-cv-03358-RMB-KMW (D.N.J. Jun. 9, 2016). On information and belief, Aurobindo Ltd. has also consented to personal

jurisdiction in this district in Hatch-Waxman actions. *See, e.g.*, Answer (Dkt. No. 18) at ¶ 21, *Astrazeneca AB et al. v. Aurobindo Pharma Ltd. et al.*, Case 3:13-cv-07298-MLC-TJB (D.N.J. Feb. 23, 2015) ("Aurobindo admits that Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. consent to jurisdiction in this Court and does not object to venue for this particular action."); Answer (Dkt. No. 10) at ¶ 7, *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd. et al.*, Case No. 1:14-cv-03306-JBS-KMW (D.N.J. Nov. 14, 2014) ("For the purposes of this action only, Aurobindo Pharma Limited consents to personal jurisdiction of this Court.").

21. On information and belief, Aurobindo Ltd. has registered to do business in New Jersey as a foreign corporation and has appointed an in-state registered agent for service of process pursuant to N.J.S.A. § 14A:4-1(1).

22. On information and belief, Aurobindo has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the ANDA seeking FDA approval to market Aurobindo's ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey.

23. On information and belief and as stated in Aurobindo's Paragraph IV Letter dated July 28, 2017 concerning Aurobindo's ANDA Product (the "Paragraph IV Letter"), Aurobindo intends to engage in the commercial manufacture, use, or sale of Aurobindo's ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of Aurobindo Ltd., acting itself and/or through its subsidiary, agent and alter ego, Aurobindo USA, will therefore cause injury to Janssen in New Jersey.

24. This Court's exercise of personal jurisdiction over both Aurobindo Ltd. and Aurobindo USA is fair and reasonable. Aurobindo Ltd. and Aurobindo USA are not unduly burdened by litigating this suit in this judicial district. New Jersey has an interest in providing a

forum to resolve Hatch-Waxman litigation, including this case, which involves the sale of products in New Jersey and parties doing business in New Jersey. This Court's exercise of jurisdiction will serve the interests of the parties and the judicial system in efficient resolution of litigation.

25. In the alternative, as to Aurobindo Ltd., this Court's exercise of personal jurisdiction over Aurobindo Ltd. is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, Aurobindo Ltd. is a company organized and existing under the laws of India, with a principal place of business in Telangana, India.

26. Under Rule 4(k)(2), for a claim arising under federal law, jurisdiction in any federal court is proper where a defendant is (1) not subject to general jurisdiction in any state, and (2) exercise of jurisdiction is consistent with the United States Constitution and laws.

27. Aurobindo Ltd. has availed itself of the laws of the United States by, among other things, seeking FDA approval for its ANDA Products and other generic pharmaceutical products. Aurobindo Ltd. also has invoked the jurisdiction of the courts of the United States, including in this judicial district.

28. Litigating in the District of New Jersey would not burden Aurobindo Ltd. unduly. Among other things, according to its website Aurobindo's U.S.-based corporate office is located in East Windsor, New Jersey. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Janssen has a substantial interest in obtaining convenient and effective relief for violations of its property interests. And the states also have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

29. For the reasons above, venue is also proper in this Court pursuant to 28

U.S.C. §§ 1391 and/or 1400(b).

30. Aurobindo Ltd. and Aurobindo USA consent to personal jurisdiction and venue in this judicial district for purposes of this action.

BACKGROUND

31. On August 27, 2013, the U.S. Patent and Trademark Office ("PTO") issued the '987 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '987 Patent is attached hereto as Exhibit A.

32. Janssen Sciences Ireland UC holds title to the '987 Patent.

33. The '987 Patent expires on February 16, 2024.

34. The FDA has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '987 Patent does not expire until August 16, 2024.

35. On April 20, 2010, the PTO issued the '645 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '645 Patent is attached hereto as Exhibit B.

36. Janssen Sciences Ireland UC holds title to the '645 Patent.

37. The '645 Patent expires on December 26, 2026.

38. The period of pediatric exclusivity applicable to the '645 Patent does not expire until June 26, 2027.

39. Janssen Products, L.P. is the holder of approved New Drug Application No. 21-976 for PREZISTA®.

40. Janssen sells Janssen's PREZISTA® in the United States.

41. PREZISTA® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

42. The FDA's "Orange Book" also lists patents associated with approved drugs. The '987 and '645 Patents are listed in the "Orange Book" in association with PREZISTA®. The claims of the '987 and '645 Patents cover PREZISTA®.

43. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit C.

44. Janssen Sciences Ireland UC holds title to the '015 Patent.

45. The '015 Patent expires on June 21, 2023.

46. On September 29, 2009, the PTO issued the '408 Patent, entitled "Method for the Preparation of (3R,3aS,6aR) Hexhydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit D.

47. Janssen Sciences Ireland UC holds title to the '408 Patent.

48. The '408 Patent expires on May 6, 2025.

49. The '015 Patent and the '408 Patent claim processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF"), an essential component of darunavir.

50. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products which are made by a processes patented by the '015

and '408 Patents prior to their expiration.

51. On information and belief, Aurobindo's preparations include, but are not limited to, the development of Aurobindo's ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

52. On information and belief, Aurobindo intends to use the processes claimed in the '015 and '408 Patents to prepare the bis-THF component of Aurobindo's ANDA Products.

53. On information and belief, that bis-THF is incorporated into and present in the drug substance (darunavir) in Aurobindo's ANDA Products, intact and without material change from the bis-THF made by use of Janssen's patented processes.

54. On information and belief, the bis-THF resulting from Janssen's patented processes is an essential component of Aurobindo's ANDA Products.

55. The processes claimed in the '015 and '408 Patents are important for the commercial-scale manufacture of bis-THF. These processes have been infringed by other generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '015 and '408 Patents. *See* Consent Judgment and Order against Hetero Defendants (Dkt. No. 52), *Janssen Prods., L.P. et al. v. Hetero Labs, Ltd. et al.*, Case No. 2:13-cv-01444-WHW-CLW (D.N.J. Oct. 15, 2015) (judgment as to the '015 and '408 Patents); Consent Judgment and Order against Teva Defendants (Dkt. No. 804), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '015 and '408 Patents); Consent Judgment and Order against Cipla Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015) (judgment as to the '015 and '408 Patents); Order Modifying Judgment against Lupin Defendants (Dkt. No. 1075), *Janssen Prods.*,

L.P. et al. v. Lupin Ltd. et al., Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Jun. 21, 2016) (judgment as to the '015 Patent).

56. On information and belief, Aurobindo Ltd., acting itself or through its subsidiary, alter ego, and agent, Aurobindo USA, submitted Aurobindo's ANDA to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of Aurobindo's ANDA Products. Aurobindo's ANDA has been assigned ANDA No. 21-0677.

57. On information and belief, Aurobindo Ltd. and Aurobindo USA collaborated in the research, development, preparation and filing of the ANDA and DMF for Aurobindo's ANDA Products.

58. On information and belief, Aurobindo USA is Aurobindo Ltd.'s authorized U.S. agent for the ANDA and the DMF.

59. On information and belief, Aurobindo USA will market and/or distribute Aurobindo's ANDA Products if the ANDA is approved by the FDA.

60. On information and belief, Aurobindo Ltd. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of the ANDA.

61. On or about July 31, 2017, Janssen Sciences Ireland UC and Janssen Products, L.P. received Aurobindo's Paragraph IV Letter stating that Aurobindo has submitted the ANDA to the FDA, seeking approval to manufacture, use, and sell Aurobindo's ANDA Products prior to the expiration of the '987 and '645 Patents.

62. Aurobindo's Paragraph IV Letter stated that Aurobindo's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '987 and '645 Patents are not infringed.

63. Aurobindo does not dispute that the claims of the '987 and '645 Patents are valid.

64. Upon receiving Aurobindo's Paragraph IV Letter, Janssen promptly and repeatedly requested production of samples of Aurobindo's ANDA Products (tablets and API) and information concerning Aurobindo's manufacturing processes, including Aurobindo's DMF and manufacturing batch records, in order to evaluate infringement of Janssen's patents protecting PREZISTA®.

65. Aurobindo agreed to produce the requested samples and manufacturing information. However, despite repeated follow up by Janssen since receiving Aurobindo's Paragraph IV Letter, as of the filing of this complaint, Aurobindo still has not produced the samples and manufacturing information.

66. Specifically, on September 1, 2017, Aurobindo finally produced its DMF after a month of delay and repeated follow up by Janssen. That same day, counsel for Janssen immediately informed Aurobindo that the DMF "does not contain any of the requested information regarding the manufacture of the bis-THF component of [Aurobindo's ANDA Products], which is "necessary to assess infringement of Janssen's process patents." Counsel for Janssen further informed Aurobindo that "time is very short" due to the tight deadlines under the Hatch-Waxman Act.

67. On September 5, 2017, Aurobindo produced manufacturing batch records. That same day, counsel for Janssen immediately informed Aurobindo that the production contained "batch records for the drug product, not the drug substance or its bis-THF component," and that "[a]s a result, we still have none of the necessary information about the manufacture of the bis-THF component that Aurobindo agreed to produce."

68. Aurobindo still has not produced the manufacturing information for the bis-THF component of Aurobindo's ANDA Products despite repeated requests. Aurobindo's withholding of needed manufacturing information has impeded Janssen's ability to evaluate infringement of the '015 and '408 Patents.

69. Aurobindo's failure to produce manufacturing information for the bis-THF component of its ANDA Products is consistent with the conclusion that the processes invented by Janssen and covered by the '015 and '408 Patents will be used to manufacture bis-THF for Aurobindo's ANDA Products. On information and belief, Aurobindo continues to withhold its manufacturing information because the bis-THF component of its ANDA Products is made using the processes claimed in Janssen's '015 and '408 Patents and the importation, use, sale, and/or offer for sale of Aurobindo's ANDA Products would infringe the '015 and '408 Patents.

70. Aurobindo has also failed to produce the requested samples of API and tablets.

71. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '987 and '645 Patents, either literally or by the doctrine of equivalents.

72. The '987 and '645 Patents have been infringed by other generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '987 and '645 Patents. *See* Consent Judgment and Order against Teva Defendants (Dkt. No. 804), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '645 Patent); Consent Judgment and Order against Teva Defendants (Dkt. No. 13), *Janssen Prods., L.P. et al. v. Teva Pharms. USA, Inc. et al.*, Case No. 2:13-cv-07576-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '987 Patent); Consent Judgment and Order against Cipla

Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015) (judgment as to the '645 and '987 Patents); Order Modifying Judgment against Lupin Defendants (Dkt. No. 1075), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Jun. 21, 2016) (judgment as to the '645 Patent).

73. On information and belief, Aurobindo had actual and constructive notice of the '987, '645, '015 and '408 Patents prior to the filing of the ANDA seeking approval of Aurobindo's ANDA Products, including through judgments in Janssen's favor against other generic manufacturers in this Court.

74. On information and belief, Aurobindo has made and continues to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import Aurobindo's ANDA Products prior to the expiration of the '987, '645, '015 and '408 Patents.

75. On information and belief, Aurobindo's actions include, but are not limited to, the development of Aurobindo's ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

76. On information and belief, Aurobindo Ltd. and Aurobindo USA continue to seek FDA approval of the ANDA and intend to collaborate in the commercial manufacture, marketing and sale of Aurobindo's ANDA Products (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves Aurobindo's ANDA.

77. Plaintiffs commenced this lawsuit within 45 days of the date they received Aurobindo's notice of ANDA No. 21-0677 containing a Paragraph IV certification.

COUNT I

Infringement of the '987 Patent by Aurobindo under 35 U.S.C. § 271(e)(2)(A)

78. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 77 hereof, as if fully set forth herein.

79. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed the '987 Patent, either literally or under the doctrine of equivalents, by submitting ANDA No. 21-0677 with a Paragraph IV certification and seeking FDA approval of ANDA No. 21-0677 to market Aurobindo's ANDA Products prior to the expiration of the '987 Patent.

80. On information and belief, Aurobindo's commercial manufacture, importation, use, sale and/or offer for sale of Aurobindo's ANDA Products prior to the expiration of the '987 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '987 Patent.

81. Aurobindo's Paragraph IV Letter does not dispute that the '987 Patent is valid.

82. Aurobindo had actual and constructive notice of the '987 Patent prior to the filing of ANDA No. 21-0677 seeking approval of Aurobindo's ANDA Products.

83. Janssen has no adequate remedy at law to redress the infringement by Aurobindo.

84. Janssen will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing or contributing to infringement of the '987 Patent.

COUNT II

Infringement of the '645 Patent by Aurobindo under 35 U.S.C. § 271(e)(2)(A)

85. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 84 hereof, as if fully set forth herein.

86. Under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed the '645 Patent, either literally or under the doctrine of equivalents, by submitting ANDA No. 21-0677 with a Paragraph IV certification and seeking FDA approval of ANDA No. 21-0677 to market Aurobindo's ANDA Products prior to the expiration of the '645 Patent.

87. On information and belief, Aurobindo's commercial manufacture, importation, use, sale and/or offer for sale of Aurobindo's ANDA Products prior to the expiration of the '645 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '645 Patent.

88. Aurobindo's Paragraph IV Letter does not dispute that the '645 Patent is valid.

89. Aurobindo had actual and constructive notice of the '645 Patent prior to the filing of ANDA No. 21-0677 seeking approval of Aurobindo's ANDA Products.

90. Janssen has no adequate remedy at law to redress the infringement by Aurobindo.

91. Janssen will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing or contributing to infringement of the '645 Patent.

COUNT III

Declaratory Judgment of Infringement of the '015 Patent by Aurobindo under 35 U.S.C. § 271(g)

92. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 91 hereof, as if fully set forth herein.

93. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Aurobindo regarding infringement of the '015 Patent.

94. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

95. Aurobindo's actions, including, but not limited to, the filing of ANDA No. 21-0677 with a Paragraph IV certification and Aurobindo's systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 21-0677 indicate a refusal to change its course of action.

96. On information and belief, Aurobindo's importation, use, sale and/or offer for sale of Aurobindo's ANDA Products prior to the expiration of the '015 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '015 Patent under 35 U.S.C. § 271(g).

97. On information and belief, Aurobindo had actual and constructive notice of the '015 Patent prior to the filing of ANDA No. 21-0677 seeking approval of Aurobindo's ANDA Products.

98. On information and belief, Aurobindo's infringement of the '015 Patent is

willful.

99. Janssen has no adequate remedy at law to redress infringement by Aurobindo.

100. Janssen will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing or contributing to infringement of the '015 Patent.

COUNT IV

Declaratory Judgment of Infringement of the '408 Patent by Aurobindo under 35 U.S.C. § 271(g)

101. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 100 hereof, as if fully set forth herein.

102. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Aurobindo regarding infringement of the '408 Patent.

103. On information and belief, Aurobindo has made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

104. Aurobindo's actions, including, but not limited to, the filing of ANDA No. 21-0677 with a Paragraph IV certification and Aurobindo's systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 21-0677, indicate a refusal to change its course of action.

105. On information and belief, Aurobindo's importation, use, sale and/or offer for sale of Aurobindo's ANDA Products prior to the expiration of the '408 Patent would infringe,

contribute to the infringement of, and/or induce the infringement of one or more claims of the '408 Patent under 35 U.S.C. § 271(g).

106. On information and belief, Aurobindo had actual and constructive notice of the '408 Patent prior to the filing of ANDA No. 21-0677 seeking approval of Aurobindo's ANDA Products.

107. On information and belief, Aurobindo's infringement of the '408 Patent is willful.

108. Janssen has no adequate remedy at law to redress infringement by Aurobindo.

109. Janssen will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing or contributing to infringement of the '408 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(a) a judgment that Aurobindo has infringed the '987 and '645 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Aurobindo's ANDA No. 21-0677 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the '987 and '645 Patents, including any additional exclusivity period applicable to those patents;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 21-0677 would constitute

infringement of the '987 and '645 Patents, or inducing or contributing to such conduct, by Aurobindo pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Aurobindo and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 21-0677, or any colorable variations thereof, until the day after the expiration of the '987 and '645 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing one or more claims of the '987 or '645 Patents;

(e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA No. 21-0677 would constitute infringement of the '015 and '408 Patents, or inducing or contributing to such conduct, by Aurobindo pursuant to 35 U.S.C. § 271(g);

(f) a declaration that Aurobindo's infringement of the '015 and '408 Patents is willful;

(g) a judgment permanently enjoining Aurobindo and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, selling, offering for sale, or using the generic darunavir tablets described in in ANDA No. 21-0677, or any darunavir product that includes a bis-THF component made by any colorable variation of the processes used to make Aurobindo's ANDA Products, until after the expiration of the '015 and '408 Patents, and from otherwise infringing one or more claims of the '015 or '408 Patents;

(h) a declaration that this case is exceptional;

(i) an award of Janssen's costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(j) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/ John E. Flaherty

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Dated: September 7, 2017

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. However, the matter in controversy involves the validity and infringement of patents previously asserted in this Court against different generic manufacturers in the following actions presided over by the Honorable William H. Walls:

- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 10-cv-05954-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Hetero Drugs, Ltd. et al.*, Civil Action No. 13-cv-01444-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 13-cv-03891-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Teva Pharms. USA, Inc. et al.*, Civil Action No. 13-cv-07576-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 14-cv-01370-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Cipla Ltd. et al.*, Civil Action No. 14-cv-05093-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Cipla Ltd. et al.*, Civil Action No. 15-cv-02549-WHW-CLW (D.N.J.); and
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 16-cv-01032-WHW (D.N.J.).

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